

CLINICAL RESEARCH

A multicentre observational study to ascertain the role of homoeopathic therapy in Urolithiasis

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Abstract : Study was aimed to ascertain the role of homoeopathic medicines in Urolithiasis. A prospective, multicentre observational study was conducted by Central Council for Research in Homoeopathy (CCRH) from October 2005 to January 2010 to find the usefulness of homoeopathic medicines in cases of Urolithiasis. 901 cases were screened, out of which 311 cases were enrolled and 220 cases were analyzed in this study. The symptoms pertaining to urolithiasis were assessed before and after treatment. Pain, Dysuria and Haematuria were graded from 0-3 as per severity of complaints. Calculi were graded as per Number, Size and Position of calculi. The difference between the scores was assessed by using 'Wilcoxon sign rank test' in SPSS software (ver. 16). Out of 220 cases, there was expulsion of calculi in 106 cases (single calculus in 76 cases, multiple calculi in 30 cases) and in 114 cases, calculi remained but the symptom score reduced, indicating improvement in the case. The symptom score at baseline and after treatment was analysed and found statistically significant ($P<0.005$). The medicines found most useful were *Lycopodium clavatum* in 40.9% ($n=90$) cases; *Sulphur* in 12.3% ($n=27$) cases; *Pulsatilla nigricans* in 8.2% ($n=18$) cases; *Nux vomica* in 6.2% ($n=14$) cases and *Cantharis vesicatoria* in 5.9% ($n=13$) cases. Treatment with homoeopathic medicines showed positive response in dissolution/expulsion of calculi. Further validation of these results is needed by conducting randomized clinical trial.

Keywords: homoeopathy; urolithiasis; lycopodium clavatum; cantharis vesicatoria; multicentre.

Introduction

The process of forming stone in urinary tract i.e. kidney, bladder and ureter is referred to as 'Urolithiasis'. Urinary calculi are one of the most common diseases of the urinary tract. When urine becomes supersaturated with insoluble materials, because excretion rates are excessive and/or because water conservation is extreme, crystals form and may grow and aggregate to form calculi. Urine supersaturation can be increased by dehydration or by over excretion of calcium oxalate, calcium phosphate, cystine or uric

acid. Stones of less than 5 mm diameter usually pass spontaneously.¹ Stones of size 5-7 mm have a modest chance (50%) of passage and those greater than 7 mm almost always require surgical intervention.²

The overall probability of forming calculi varies in different parts of the world. The risk of developing urolithiasis in normal adults appears to be lower in Asia (1 to 5%) than in Europe (5 to 9%) and in North America (12% in Canada, 13% in the U.S.). The highest risk was reported in Saudi Arabia (20.1%).³ In India, upper and lower urinary tract stones occur frequently but the incidence shows wide regional variation. The incidence of urinary calculi is comparatively low in the southern parts of the country compared to other parts. The prevalence of urolithiasis is as high as 7.6% in Satpura part of Maharashtra. Pendse et al had reported a high and progressively increasing incidence of urolithiasis in Udaipur and some other parts of Rajasthan, the

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western part of India. With its multifactorial etiology and high rate of recurrence, urolithiasis remains a medical challenge. Various studies from India have also documented that calcium oxalate forms the major constituent of urinary calculi in India.⁴

Recurrence rates are estimated at about 10% per year, totaling 50% over a 5-10 year period and above 75% over 20 years.⁵ Age and sex differentials in urinary stone formers are substantial: more common in males of 30-40 years of age in the industrialized countries and in children under 10 years in the developing countries. Racial differentials are also noted; blacks appear to suffer less frequently than whites.⁶

Around 12.7% of India's population depends solely on homoeopathy for their health care.⁷ Homoeopathy has been proved to be a boon for patients in whom surgery is a risky affair such as aged ones, hypertensive and diabetics or those who are in search of an alternative to surgery. Homoeopathy recognizes man as the multi-dimensional composite entity where mind, body and spirit are viewed as an indivisible entity and union.⁸

So far, no systematic study or research work has been conducted on urolithiasis in the homoeopathic field. Central Council for Research in Homoeopathy (CCRH) has undertaken a clinical trial to assess the role of homoeopathic medicines in urolithiasis at its different institutes. In the present study, homoeopathic treatment has been rendered on the central tenet of homoeopathic prescribing i.e. individualization. Remedy has been selected as per demand of the constitution, totality of symptoms of each patient. Such classical homoeopathic approach promotes the dissolution/ expulsion of calculi from urinary tract and relieves the symptoms of patients.

OBJECTIVES

Primary objective:

To ascertain the role of homoeopathic medicines in Urolithiasis.

Secondary objectives:

- To establish characteristic indications of medicines found useful.
- To ascertain additional/clinical indications, if any, in respect of homoeopathic medicine(s) used during the study.

MATERIAL & METHOD

Study design

This was a prospective, open multicentre observational study conducted by CCRH at its Central Research Institutes (Homoeopathy) at NOIDA (Uttar Pradesh) & Kottayam (Kerala), Homoeopathic Drug Research Institute, Lucknow (Uttar Pradesh), Regional Research Institutes (Homoeopathy) at Gudivada (Andhra Pradesh) & Jaipur (Rajasthan). The study protocol was in accordance with the Helsinki's declaration on human experimentation.⁹ The necessary ethical clearance was obtained from the Ethical Committee of CCRH. Cases having signs and/or symptoms of Urolithiasis who came for treatment in general Out Patient Department (OPD) of above mentioned Institutes were considered for this study. The screening of the cases was done by carrying out investigatory procedures like Ultrasound and X-ray of

Table 1: Urolithiasis Symptom Score (USS) Chart.

Urolithiasis Symptom Score				
	(Circle relevant number on each line)			
1. Pain/colic	0 No pain	1 Mild pain	2 Moderate pain	3 Severe pain
2. Haematuria	0 No haematuria	1 Microscopic	2 Persistent	3 Gross
3. Dysuria	0 No dysuria	1 Mild dysuria	2 Moderate dysuria	3 Severe
4. Stone		1 Single stone	2 Multiple stone	
5. Size of stones	0 Gravel < 03mm	13 mm - < 4 mm	24 mm - < 5 mm	35 mm and above
6. Position of stone kidney	0 no stone in kidney	1 Pelvic ureteric junction	2 Pelvis of kidney	3 Calyces of kidney
7. Position of stone ureter	0 no stone in ureter	1 Lower part of urater	2 Middle of urater	3 Upper part of urater
8. Position of stone bladder	0 no stone in bladder	1 Base of bladder	2 Intramural urater	

Total scoring – 22, 1-7 mild, 8-14 moderate, 15-22 severe.

Symptoms score – (Some of 8 circled numbers)

kidney, ureter and bladder (KUB). Intensity of pain/colic, haematuria, dysuria, were graded from 0-3. Calculi (single or multiple), size of calculi (s), position of calculi (kidney, ureter, bladder-above downwards) were assessed in each case. (Table 1)

Cases conforming to the predefined inclusion as envisaged in the protocol were included for the study. Baseline and each follow up assessment was conducted by Consultant Surgeon. For each case, analysis and evaluation of symptoms, constructing totality of symptoms and repertorization was done. Repertorization was done using Complete repertory on Homoeopathic software 'Cara'. Similimum for the cases was chosen after consulting Homoeopathic Materia Medica by William Boericke & H.C. Allen.

Inclusion criteria

Cases (symptomatic and asymptomatic) with radiological evidence (X-ray and Ultrasound (KUB) of calculi in kidney/ureter/ bladder and no history of expulsion of calculi after the radiological investigation within one month period.

Exclusion criteria

Cases with moderate/severe hydronephrosis, uremia, recurrent urinary tract infections (other than calculi), acute retention of urine for more than 24 hours, hyperparathyroidism, gross developmental defects or structural abnormality of kidney, other systemic diseases like cardiovascular, endocrinal diseases or systemic infections or on other treatment therapies, kidney function impairment, stag horn calculus and calculi in poles of kidney.

Treatment plan

Homoeopathic medicine was prescribed as per instructions given in Hahnemann's Organon of Medicine.¹⁰ The symptom score and investigation findings were regarded as parameter to change the prescription up to two times, if the first prescription did not work. If aggravation continued or no improvement was noticed after change of medicine twice, the case was declared as clinically failed and excluded from study. These cases were referred for other mode of treatment. During study, if any acute illness occurred, it was treated with homoeopathic medicines on the basis of acute totality.

Selection of medicine

History of each individual case was recorded on structured proforma. After analysis and evaluation of the symptoms, totality was formed and repertorised

using Complete Repertory and homoeopathic software 'Cara'. Selection of medicine was made out of the medicines that fetched the highest value on Repertorisation and verified from homoeopathic materia medica following the principles of Homoeopathy. The homoeopathic medicines were procured from the approved GMP certified pharmaceutical company.

Potency, doses and repetition

Indicated medicine in 30 centesimal (C) potency, single dose i.e. 4 pills (size 30) was administered to the patient on empty stomach followed by placebo. Medicine was not repeated as long as the improvement in symptoms of the patient continued. When improvement stopped, the same medicine was repeated in same potency. During follow up, changes in signs and symptoms of each case were noted and single dose of next higher potency (200C) of the same medicine was administered in those cases that had no further improvement or improvement lasted for a short duration. Medicine up to 1000C potency was prescribed in the same manner. Medicine was changed if required, but maximum 03 indicated medicines were tried in each case. A case is labelled as clinical failure if the complaints persisted or worsened even after the 03 best indicated medicines in 30C, 200C and 1000C potencies were tried but failed.

Auxiliary measures

Urolithiasis is the multidimensional disorder with several underlying disorders of metabolism. Hence diet plays an important role, especially in prevention of re-formation of calculi. Inappropriate dietary habits, overweight and lifestyle are suggested to contribute considerably to the increasing incidence and prevalence of urolithiasis. Although a high fluid supply has been demonstrated to decrease the incidence of Urolithiasis keeping this in view patients were advised to reduced food containing calcium, oxalate etc. and increase water intake.¹¹

Outcome assessment and statistical analysis

Each enrolled case was followed-up every month and Ultrasonography & X-ray of KUB at every 3rd, 6th, 9th and 12th month were done to assess/compare the number, size and location of the calculus. Cases who visited minimum three times during one year of follow up, were considered as complete cases and intention to treat analysis was done for these cases. On the basis of score obtained from USS index chart, cases according to intensity were grouped into *mild* (1-7), *moderate* (8-14) and *severe* (15-22). Non parametric

test of 'Wilcoxon sign rank test' was applied to see the difference between the intensity of score before and after treatment (Table-2). The analysis was conducted through the software SPSS (ver.16). The percentage changes of symptom score from baseline to end of the treatment were calculated by using following formula:

$$\text{Percentage} = \frac{\text{score at Baseline} - \text{score at end} \times 100}{\text{score at Baseline}}$$

Outcome of the treatment was measured in gradation as *marked improvement* (75 to < 100% improvement), *moderate improvement* (50 to < 75% improvement), *mild improvement* (25 to < 50% improvement), *no significant improvement* (< 25% improvement), *static* (no change), and *worse* (increase in symptoms score).

Table 2: Total symptom score at entry and at end of the treatment of urolithiasis.

		Median/IQR at entry	Median/ IQR at end	Z Value	P-value
Symptom score	220	11/10-13	5/0-8	12.744	0.001*
Mild (1-7)	6	7/7-7	0/0-0	2.226	0.026*
Moderate (8-14)	195	11/10-12	6.5/5-7	11.987	0.001*
Severe (15-22)	19	16/15-16	8/8-9	3.836	0.001*

Wilcoxon sign rank test significant at $P < 0.05^*$

RESULTS

311 cases were enrolled in the study, out of which 220 cases, [males (n=161), females (n=59)] were followed up for one year. 91 cases were dropped out due to no follow up during the study. Details of the patients screened and enrolled were described in Figure 1. Mean age recorded was 31.6 ± 5.58 years in age group of 20-40 years. In maximum (n=117) cases, duration of illness recorded was below 06 months (Table 3).

Non parametric test of 'Wilcoxon sign rank test' was used to find out the changes in symptom score before and after the treatment. Intensity of the change in symptom score showed statistical significance at $p < 0.05$ (Table 2). The symptom 'Pain' was found in 218 (99.1%) cases at the baseline, but after treatment remained only in 31 (14.1%) cases. Haematuria in 64 (29.1%) cases, dysuria in 163 (74.1%) cases were present at the time of enrollment and persisted in 18

Figure 1: Flowchart of the study details

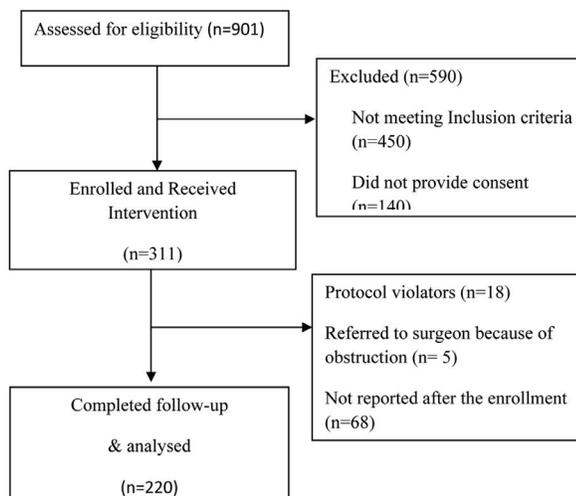


Figure 2: Status of calculi before and after the treatment

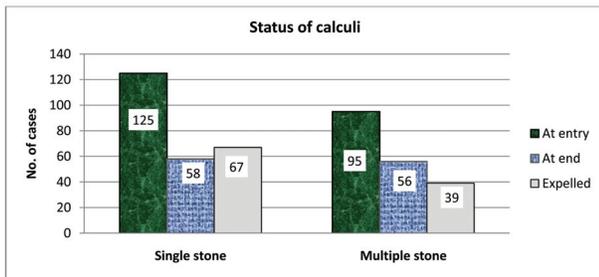


Figure 3: Calculus of 16.9 mm size expelled from left kidney with medicine Sarsaparilla.



Table 3: Demographical details of the cases at Baseline.

Details	No. of cases (%) (220)	Mean±SD
Age group (in years)		
1 - 20	17(7.7)	16.52±3.39
21- 40	38(62.7)	31.6±5.58
41 - 60	160(27.3)	48.18±5.53
60 and above	5(2.3)	66.8±1.78
*Weight (Metric BMI categories)		
Underweight	24(10.9)	50.37±15.67
Normal weight	131(59.5)	58.94±8.30
Overweight	47(21.4)	70.18±8.78
Obesity	18(8.2)	76±15.93
Duration of disease (in months)		
Less than 6	117(53.2)	2.15±2.01
6 - 12	28(12.7)	10.57±1.81
12 - 60	57(25.9)	32.54±11.89
60 - 120	9(4.1)	86.66±20.59
More than 120	9(4.1)	226.22±36.33
Intensity		
• Mild (1-7)	6 (2.7)	6.83±0.408
• Moderate(8-14)	195(88.6)	10.98±1.576
• Severe (15-22)	19(8.6)	15.79±0.976
Number of stones		
• Single	125(56.81)	-
• multiple	95(43.19)	-

*Underweight = <18.5, Normal weight = 18.5-24.9, Overweight = 25-29.9, Obesity = BMI of 30 or greater

(8.2%) cases and 14 (6.4%) cases respectively after completion of treatment (Table 4).

Comparison of single and multiple calculi at baseline and at the end of treatment showed that single calculus at baseline was present in 125 cases (calculus size minimum 06 mm and maximum 22 mm), out of which calculi were expelled in 76 cases (calculi size minimum 06 mm & maximum 16.9 mm). In 49 cases (calculi size minimum 1mm & maximum 18 mm) there was reduction in size of calculi which was statistically

significant ($P<0.05$). Multiple calculi were present in 95 cases (calculi size minimum 2.6 mm & maximum 38 mm) at baseline and expelled in 30 cases (calculi size minimum 03 mm & maximum 13 mm) after treatment, remaining 65 cases (calculi size minimum 04 mm & maximum 08 mm) showed reduction in size of the calculi (Figure 2).

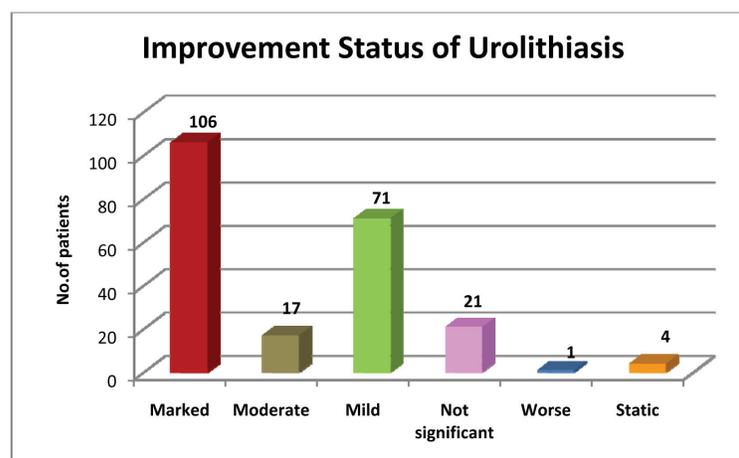
Results showed that in 12 cases, single calculus was converted into multiple calculi and in 21 cases, multiple calculi were reduced to single calculus at the

Table 4. Changes in symptoms of Urolithiasis before and after treatment.

Symptoms	Before Treatment No. of cases (%)	After Treatment No. of cases (%)	Median/ IQR		Z value	P value
			Before Treatment	After Treatment		
Pain /Colic	218(99.1)	31(14.1)	2/2-3	0/0-0	12.878	0.000*
Haematuria	64(29.1)	18(8.2)	0/0-1	0/0-0	5.804	0.000*
Dysuria	163(74.1)	14(6.4)	2/0-2	0/0-0	11.137	0.000*
Calculi	220(100)	114(51.9)	1/1-2	1/0-2	9.306	0.000*
Size of calculi		10.278	0.000*			
calculi < 3mm	0	3 (2.6)	NA	0/0-0		
3mm < 4mm	8(3.6)	7(6.1)	1/1-1	1/1-1		
4mm < 5mm	19(8.6)	16(14.1)	2/2-2	2/2-2		
5mm and above	193(87.7)	88(77.2)	3/3-3	3/3-3		
Position of calculi in kidney	164(73.63)	97(44.09) ¹	3/3-3	0/0-3	8.512	0.000*
Position of calculi in ureter	31(14.09)	3(1.36) ₂	0/0-0	0/0-0	5.464	0.000*
Position of calculi in urinary bladder	1(0.45)	1(0.45) ₃	0/0-0	0/0-0	NA	0.102**
Position of calculi in Kidney + Bladder	3 (1.36)	1 (0.45)	NA	NA	1.604	0.109**
Kidney + Ureter	19 (8.63)	8 (3.6)	NA	NA	3.831	0.001*
Position of calculi in bladder+ Ureter	1 (0.45)	1 (0.45)	0/0-0	0/0-0	NA	NA
Position of calculi in Kidney+ bladder+ Ureter	1 (0.45)	1 (0.45)	0/0-0	0/0-0	NA	NA

Wilcoxon sign rank test significant at $P < 0.05^*$, not significant at $P > 0.05^{**}$.

Figure 4: Degree of improvement of Urolithiasis (n=220) symptoms score at the end of the study.



end of treatment. Within three months of starting the treatment, in 56 cases calculi were expelled, within 06 months in 67 cases within 09 months of treatment in 74 cases and within 12 months of treatment in 106 cases. During the study, periodical changes were noted in size, number and location of calculi ascertained through Ultrasonography and X-ray of KUB.

Calculi were present in kidney in 164 cases, in urinary bladder 01 case and in ureter 31 cases at baseline and calculi remained in kidney in 88 cases, in urinary bladder 01 case and reduced to 03 cases in ureter after the treatment. In 19 cases, calculi were present both in calyces of kidney and ureter after treatment (Figure 3).

In this prospective observational study, total 19 medicines were used. The medicines found most useful are *Lycopodium* (40.9%), *Sulphur* (12.3%),

Pulsatilla nigricans (8.2%), *Nux vomica* (6.4%), *Cantharis versicoloria* (5.9%), *Calcarea carbonica* (5.0%), *Berberis vulgaris* (4.5%), *Phosphorus* (3.2%), *Belladonna* (2.7%), *Arsenic album* (2.3%), *Argentum nitricum* (1.8%), *Apis mellifica* (0.3%), *Sepia* (0.3%) and *Sarsaparilla* (0.2%). *Colocynthis*, *Nitric acid* and *Stramonium* was prescribed in one patient each. The effects of these medicines were found statistically significant ($P < 0.05$) (Table 5). Characteristic indications of medicines were verified during the study (Table 6).

At the end of the study, out of 220 cases, 48.18% (n=106) cases showed marked improvement, 7.72% (n=17) cases moderate improvement, 32.3% (n=71) cases mild improvement, 9.54% (n=21) cases no significant improvement, 1.36 (n=03) cases did not improve, 0.45% (n=01) case got worse and 0.45% (n=01) case was static (Figure 4).

Table 5: List of the medicines used and their significance in urinary symptoms.

Name of the medicine improvement	No. of patients-Mild prescribed	Percentage (%)	Marked improvement	Moderate improvement	Mild improvement	Not Significant improvement	worse	Static
Lycopodium clavatum	90	40.91	41	6	31	11	0	1
Pulsatilla nigricans	18	8.18	9	2	5	2	0	0
Cantharisversicolor	13	5.91	3	2	6	0	1	1
Berberis vulgaris	10	4.55	6	1	1	2	0	0
Belladonna	6	2.73	3	1	2	0	0	0
Argentum nitricum	4	1.82	3	0	1	0	0	0
Sepia	3	1.36	2	0	1	0	0	0
Natrum muriaticum	2	0.91	1	0	1	0	0	0
Colocynth	1	0.45	0	0	1	0	0	0
Stramonium	1	0.45	1	0	0	0	0	0

Table 6: Clinically verified characteristic indications of most useful medicines.

S. No.	Name of Medicine	Indications
1.	<i>Lycopodium clavatum</i> ²⁰	Renal colic from right ureter to bladder. Haematuria. Pain in back before urination, > after passing urine. Polyuria during the night. Desire for warm food, sweets; voracious appetite, and increased thirst. Urine milky, turbid, with red sediment, burning hot. Urine passes slowly, must strain.
2	<i>Sulphur</i> ^{21,22}	Ineffectual urging to urinate; incontinence of urine especially at night. Burning & itching in urethra during urination, lasts long after. Large quantities of colourless urine, greasy particles in it. Mucous and pus in the urine. Urination involuntary while passing flatus or on coughing. Parts feel sore over which urine passes.
3	<i>Nux vomica</i> ²³	Fastidious, irritable, headstrong. Urging to urinate from spasmodic sphincter. Frequent calls, little urine is passed. Ineffectual urging to urinate, spasmodic pain & strangury. While urinating, itching in urethra and pain in neck of bladder.
4	<i>Calcarea Carbonica</i> ²⁴	Fat, fair, flabby; perspiring profusely. Craving for egg. Great sensitiveness to cold. Sudden, irresistible urge to urinate; Urine dark brown, sour or of strong smell; white sediment.
5	<i>Cantharis versicolor</i> ²⁵	Burning, cutting pain before, during & after urination. Constant desire for urination. Intolerable tenesmus. Urine scalds & passed drop by drop. Urine jelly like, shreddy.

DISCUSSION

Similar to previous studies male dominance and prevalence in age group 20-40 years was recorded in urinary complaints, males being 161 (73.2%) and females 59 (26.8%) and maximum cases 138 (62.7%) were in the age group of 20-40 years.⁶ Minimum age of patient found was 09 years and maximum was 69 years. As compared to other studies¹² where risk of calculi formation is more in overweight patients, our study does not support such observation as maximum number of cases had normal body weight (Table 3).

Geographical variation and socio economic status impact on the dietary habits¹³ has been observed in one of the units at Jaipur, Rajasthan where environment and climatic situation favors fluid loss and dietary habits which play a major role in the formation of calculus.¹⁴ Drinking hard water, taking foods rich in minerals as Bajara (Pearl Millet), more use of dairy products and dry hot climate favoring excessive loss of water are the factors associated with the higher incidence.¹⁵

Homoeopathic constitutional remedies selected on the basis of individualization were successful in the treatment of urolithiasis cases, causing expulsion/dissolution of calculi and relief of symptoms of the patients, similar to the results of other studies.^{16,17} After completion of study when we compare duration of illness with improvement outcome, it has been

observed that cases enrolled with recent duration of complaints, viz. duration of illness between 0-6 months, 117 cases responded positively which was statistically significant ($P=0.001$) and also cases with long duration of illness responded well ($P=0.001$) to homoeopathic medicines.

During the treatment, *Sulphur* was prescribed in 27 (12.3%) cases and showed marked improvement in 13 (48.14%) cases, moderate improvement in 09 (33.33%) cases, mild in 01 (3.70%) case, not significant in 01 (3.70%) case and no improvement in 03 (11.11%) cases. This medicine is not mentioned in any repertory against the rubric of kidney/bladder calculi but found very useful in expulsion of calculi and relieved symptoms in maximum cases. *Sarsaparilla* is commonly used for right sided kidney complaints¹⁸, but in our study, this medicine could cause expulsion of calculi from the left kidney of size 16.9 mm (Figure 3). This is a valuable observation for our profession, as it adds to the clinical symptom in Materia Medica and Repertory fulfilling our secondary objective of study. In another paper, the useful medicines were *Calcarea carbonica*, *Lycopodium clavatum*, *Pulsatilla nigricans*, *Sulphur*.¹⁷ Our study result supports these findings. In acute exacerbation of disease, the medicines like *Belladonna*, *Cantharis*, *Mag. phos.*, *Colocynth* etc. were used with positive results.

One of the studies on systemic orientation of classical homoeopathic philosophy supports the need

for development of new, multidimensional outcome measures for clinical research in Homoeopathy beyond the disease-specific and health related quality of life scale available from conventional medical research.¹⁹ Limitation of this study was that we could not label cases as cured because the duration of study was only one year. The study could have yielded better result if the duration was for 3 years where the recurrence of calculi formation could have also been judged.

CONCLUSION

This was an observational study with positive results and these results need further validation by conducting clinical trials. Based on this study result, CCRH intends to take up Randomized Controlled Trial keeping in won the drugs which have been found useful in cases of Urolithiasis. This study proved the usefulness of wholistic approach in treatment considering individuality of patients and not just disease symptoms for remedy selection and outcome assessment.

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